

bioMerieux Recalls NucliSENS easyMAG Magnetic Silica and NucliSENS Magnetic Extraction Reagents due to Potential Inaccurate Test Results

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- NucliSENS easyMAG Magnetic Silica and NucliSENS Magnetic Extraction Reagents
- Lot Numbers: [See List Below](#)
- Distribution Dates: May 03, 2016 to August 18, 2016
- Devices Recalled in the U.S.: 376

Device Use

The NucliSENS easyMAG Magnetic Silica is used to extract nucleic acids (RNA or DNA) which contain genetic material from biological samples, such as blood, tissue, etc., which could then be used in various applications for molecular infectious disease assays, molecular oncology assays, and molecular genetics assays.

The NucliSENS Magnetic Extraction Reagents are accessory products to be used with the NucliSENS miniMAG, eMAG, and easyMAG systems. These products enable the automated extraction of RNA/DNA from biological samples. These products are intended for in vitro diagnostic use by health care professionals.

Reason for Recall

This is a continuation of [bioMerieux's previous recall \(/MedicalDevices/Safety/ListofRecalls/ucm516437.htm\)](#) for NucliSENS easyMAG Magnetic Silica. The firm has identified additional affected product lots, and an additional product, the NucliSENS Magnetic Extraction Reagents, which have been determined to be in scope of the previous recall.

bioMerieux is recalling the NucliSENS reagents and accessory products due to a quality problem of the magnetic silica (MagSil) component. MagSil is used to extract and purify genetic material from patient samples. Kits with the affected lots of the magnetic silica may not be able to fully extract nucleic acids from the sample and detect infection or provide proper diagnosis. The detection problem could lead to a risk of false negative results, invalid results, or under-

quantification for clinical laboratory tests. This error may result in inappropriate treatment or delay in treatment. The use of the affected product may cause serious adverse health consequences, including death.

To help reduce the risk to patients, bioMerieux recommends that labs use internal extraction controls which mimic the extracted target. See the "[What to Do](#)" section for more information.

Who May be Affected

- Laboratory personnel who interpret the results of the NucliSENS easyMAG nucleic acid extraction or MiniMAG systems.
- Health care providers who rely on results from the NucliSENS easyMAG nucleic acid extraction or MiniMAG systems.
- All patient groups receiving a diagnosis from laboratories using the NucliSENS easyMAG nucleic acid extraction or MiniMAG systems.

What to Do

On November 23, 2016, bioMerieux sent Urgent Product Safety Correction Notices to affected customers. The notice asked customers to:

- Distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred this product.
- Use systematically an extraction internal control which mimics the extracted target (with same nature/structure), and/or external controls as recommended in the instructions for use and in good laboratory practices to detect any extraction performance issue.
- In case of a detected issue, reduce the sample input volume to 200µl.
- Discuss any concern regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.
- Contact your local customer service if you observe the issue.
- Complete and return the Acknowledgement Form by Fax to confirm receipt of this notice.

Contact Information

Customers with questions may contact bioMerieux Clinical Customer Service at (800) 682-2666 or bioMerieux Industry Customer Service at (800) 634-7656.

Date Recall Initiated

November, 23 2016

How Do I Report a Problem?

Consumers may report adverse reactions or quality problems they experienced using these devices to [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) either online, by regular mail or by FAX to 1-800-FDA-0178.

Product Information

Reference Number	System	Product Name	Silica Lots	Quantity	Expiration Date	Distribution Start Date
280133	NucliSENS easyMAG/eMAG	Magnetic Silica MagSIL	Z017KA1MS	365	28-sept-17	03-may-16
280133	NucliSENS easyMAG/eMAG	Magnetic Silica MagSIL	Z017KB1MS	362	28-sept-17	13-may-16
280133	NucliSENS easyMAG/eMAG	Magnetic Silica MagSIL	Z017LE1MS	361	28-oct-17	07-jul-16
280133	NucliSENS easyMAG/eMAG	Magnetic Silica MagSIL	Z017MA1MS	362	28-nov-17	07-jul-16
280133	NucliSENS easyMAG/eMAG	Magnetic Silica MagSIL	Z017NA1MS	364	28-dec-17	03-may-16
280133	NucliSENS easyMAG/eMAG	Magnetic Silica MagSIL	Z017NB1MS	361	28-dec-17	13-may-16
280133	NucliSENS easyMAG/eMAG	Magnetic Silica MagSIL	Z017NC1MS	360	28-dec-17	07-jul-16
280133	NucliSENS easyMAG/eMAG	Magnetic Silica MagSIL	Z017ND1MS	364	28-dec-17	25-jul-16
200293	MiniMAG	NucliSENS Magnetic Extraction Reagents.	16072701	995	28-aug-17	18-aug-16

More in Medical Device Recalls
[\(/MedicalDevices/Safety/ListofRecalls/default.htm\)](/MedicalDevices/Safety/ListofRecalls/default.htm)

2017 Medical Device Recalls (</MedicalDevices/Safety/ListofRecalls/ucm535289.htm>)

2016 Medical Device Recalls (</MedicalDevices/Safety/ListofRecalls/ucm480134.htm>)